IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF ALFRED INTOCCIA, JR. TAKEN AUGUST 9, 2013

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
ai073113, (Pages 58:19 to 59:20) **58** **19 Q If a product is inadequately tested and it is** **20 then released on the market and a lot of people are hurt** **21 by that product, if the product was inadequately tested,** **22 that's the company's fault, isn't it?** **23 A The company has a very well-defined process for** **24 developing products that -- cross-functionally, that** **59** **1 means all functions, marketing, clinical, regulatory,** **2 manufacturing, all have to follow standard operating**	**58:19-59:20** **FRE 401, 402, 403** **FDA**	

3 procedures. And you cannot skip steps. You have to 4 complete all of that, all of those activities which 5 includes testing before the product can launch. 6 So for instance, when I'm under pressure by a 7 business team, they're anxious to get a new product to 8 market, the division president is interested in my 9 launching, moving more quickly towards getting products 10 out the door and views that products are late. It's 11 because we're going through the appropriate steps, and 12 those steps take what they take in terms of timeline. 13 And one of the things that I need to do as head 14 of R&D is be assured that we follow those steps. 15 There's a sequence to them. There's a depth of testing 16 that has to be done. There's a rigor in that testing 17 that assures that the product going out the door is safe 18 and effective. 19 And that product is submitted to the FDA, and 20 the FDA clears it via different regulatory pathways.		
ai073113, (Page 310:1 to 310:13) 310 1 Q Good evening, Mr. Intoccia. Please tell the 2 jury a little bit about yourself. Introduce yourself to 3 the jury for me, please. 4 A I am a married father of three adult-stage 5 children. I live in Nashua, New Hampshire. I do enjoy 6 living in the state, the state of no income tax, the 7 state of beautiful lakes, White Mountains. I enjoy the 8 area.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

9 Q Very good. 10 A I've worked in medical devices for 39, 40 years 11 at this point. 12 Q Do you currently work for Boston Scientific? 13 A I do not.		
ai073113, (Pages 310:23 to 311:7) 310 23 Q And let's talk about your work experience in 24 research and development. Where did you first work as 311 1 an engineer? 2 A I first worked as a research and development 3 engineer for Bentley Baxter Laboratories in Irvine, 4 California, developing artificial kidneys for use in 5 dialyzer, dialysis, hemodialysis markets, and also 6 developing connective blood tubing sets for moving a 7 patient's blood to these artificial kidneys.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
ai073113, (Pages 311:16 to 317:4) 311 16 Q And when were you at Baxter? What years? 17 A '78 and '79. 18 Q And where did you go next? 19 A Next I went to C.R. Bard. I was with Bard for 20 multiple years. I believe it was 14 years I was with 21 Bard. Starting in 1979 I worked as a project engineer 22 for Bard developing cardiopulmonary bypass surgery 23 disposables. Basically it's a heart-lung machine. An 24 artificial lung is used by surgeons with patients who 312 1 are undergoing bypass surgery or heart valve surgery. 2 Q And it looks like, according to what we've 3 marked as Exhibit 451, which is a copy of your resume,	BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

4 that you had a number of positions at Bard. Is that **5 right?** **6 A I did. I moved through project engineer** **7 through engineering manager and then several years as** **8 director of new business development, which was outside** **9 of R&D, working for the marketing organization for** **10 exploration of acquisitions.** **11 And then director of R&D acting '91 to '93. And** **12 then concluded as an R&D program director for the** **13 division, again managing a large cross-functional team** **14 focusing on this Quantum membrane oxygenator, which is** **15 again an artificial lung associated with cardiac bypass** **16 surgery.** **17 Q So what -- Tell the jury what you were doing.** **18 Describe what your responsibilities were as R&D program** **19 director and director of R&D at Bard.** **20 A Program director, I managed a team of** **21 approximately 20 cross-functional individuals, dotted** **22 line; in other words, indirectly. And the job of -- My** **23 job was to -- from conception all the way through to** **24 commercialization, develop this hollow fiber membrane** **313** **1 oxygenator product, this artificial lung.** **2 So I went through the various phases associated** **3 with product development through the definition of what** **4 we're going to do, the market research associated with** **5 the -- associated with the product, interaction with the** **6 physicians, benchmarking competitive products,** **7 developing various prototypes and configurations,**		

testing the product on the bench as well as in animals to be assured that the product that we were developing was meeting the design input requirements, in other words, the product specifications. **Q Okay. And then following C.R. Bard, where did you go work next?** **A I went to Minntech Corporation in Plymouth, Minnesota, where I was the business unit general manager. So I managed a team of -- a director of sales, director of marketing, director of manufacturing, director of research and development. And it was a small business unit that had the responsibility of managing the business associated with this Biocor membrane fiber oxygenator, again another artificial lung used in open heart surgery.** **Q Another medical device?** **A Another medical device.** **314** **Q And then following Minntech, you went to, it looks like, TFX Medical. What did you do there?** **A I was a vice president of vascular access devices. So I had responsibility for the managing of the business so I had profit and loss responsibilities for that business.** **I managed the team such that we made the hard choices about where to invest, ultimately where the products would be marketed, what new products we would be investing in, what products -- the products that were manufactured, maintaining the manufacturability of**		

those products, maintaining the quality of the products. **So it was, in effect, a small business.** **And the real, I feel, advantage learning there** **was being able to function at a general manager level.** **Q And that was another medical-device company?** **A It was another medical-device company, yes.** **Q And then it looks like you went to MedSource** **Technologies for a short time in 2001. What did you do** **at MedSource?** **A I was director of engineering. It was again** **another medical company associated with endoscopy** **devices. I was there for a short period of time. So** **what I was able to do is realign personnel to have -- be** **315** **more effective. We implemented research and development** **metrics, updated the design control procedures, which** **were antiquated, and then completed a product that had** **been previously started before I was there that was** **brought to MedSource by Johnson & Johnson. It was a** **vein-harvesting device associated with varicose veins.** **Q And it looks like you were at MedSource for** **just a short time and then started at Boston Scientific** **in 2001. Is that right?** **A Yes. I moved to -- as an R&D director for** **Boston Scientific in April of 2001.** **Q Why did you move to Boston Scientific in 2001?** **A I was recruited by Boston Scientific out of** **MedSource. As part of the process of leaving TFX**		

15 Medical and looking for a new position with recruiters **16 and working and my resume in effect on the street, I was** **17 approached by Boston Scientific as a part of that** **18 initial search while I had accepted that MedSource** **19 position.** **20 And I interviewed at Boston Scientific, and I** **21 saw it as an extremely valuable role to me and something** **22 that I really wanted to do, get into the company. So I** **23 took the position as -- of R&D director, urology and** **24 women's health, when it was offered.** **316** **1 Q And you were at Boston Scientific, like you** **2 said, until 2012. During that period of time were you** **3 always in the R&D group?** **4 A I was.** **5 Q Prior to working at Boston Scientific, did you** **6 have R&D experience in these other positions that you** **7 talked about?** **8 A I did. Almost all of my experience, with the** **9 exception of director of new business development at** **10 C.R. Bard, was R&D related or general manager related.** **11 Q And did you have experience in R&D of -- in** **12 medical devices prior to coming to Boston Scientific?** **13 A I did. All of my experience for the last 39,** **14 40 years has been in medical devices.** **15 Q And when you came to Boston Scientific in 2001** **16 as the R&D director, what did you do? What were some of** **17 your responsibilities?** **18 A Responsibilities were to manage a small team of**		

19 research and development engineers. We were focusing on 20 the women's health market primarily, develop products 21 for stress urinary incontinence otherwise known as 22 slings, and developed multiple products in that area. 23 Also managed the portfolio committee for the 24 division making a determination on next areas for 317 1 investment in our R&D programs linked to, you know, 2 five-year strategic plans where the division wanted to 3 go in terms of specific markets or market areas or 4 product lines.		
ai073113, (Page 318:4 to 318:18) 318 4 Q And then you were promoted to vice president of 5 R&D in 2005. Describe for the jury how your 6 responsibilities changed from being R&D director to vice 7 president of R&D. 8 A Well as vice president of R&D you're a member 9 of the division management board. So you are providing 10 input on strategic decisions, strategic direction of the 11 division. I manage a much larger organization of 12 people. 13 There was 90 people plus, consisting of program 14 managers, engineers, scientists, all identifying either 15 new opportunities or working on specific programs that 16 had been determined by the portfolio committee as areas 17 we want to invest in for products and bringing the 18 products to market, new and improved products to market.	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

ai073113, (Pages 320:11 to 321:8) **320** **11 Q In terms of your responsibilities from 2001 to** **12 2012 at Boston Scientific, were there a number of** **13 projects that were happening in the R&D division while** **14 you were there?** **15 A Yes. Typically in play on an annual basis** **16 there were 20 to 30 projects a year that we were working** **17 on in various stages of development, anywhere from** **18 exploratory work at a very low investment level to tech** **19 deb projects, which were pre-- active projects that were** **20 solving specific technical problems associated with a** **21 product or a product line.** **22 We were trying to answer a very critical** **23 question regarding a new potential product that needed** **24 to be resolved before that project was moved into an** **321** **1 active project phase.** **2 There were approximately 14 active projects out** **3 of that let's call it 30 programs in total that were in** **4 what's called the PDP active project designation. So** **5 these were projects that decisions had been made. We're** **6 actively going to invest. We put a cross-functional** **7 team in place, and we're going to develop this product** **8 and bring it to market.**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**
ai073113, (Page 321:15 to 321:20) **321** **15 (Exhibit Number 471** **16 marked for identification)** **17 Q What is Exhibit 471?** **18 A It was a presentation that I provided on the** **19 details associated with a new-product development**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate the**	**Plaintiffs adopt and incorporate their counter designations, if any.**

20 process.	**objections set forth in their counter designations, if any.**	
ai073113, (Page 322:2 to 322:16) **322** **2 Q I want to turn your attention over to page 4.** **3 What were you depicting on this slide?** **4 A I was trying to depict at a very high-level** **5 summary of what it takes and what are the stages and** **6 steps that it takes to develop a new product within the** **7 Boston Scientific system.** **8 So there's five phases within the Boston** **9 Scientific system. It starts with a proposal and ends** **10 with commercialization of the product.** **11 At the proposal phase, which is the initial** **12 phase, there's a lot of business planning, there's a lot** **13 of project planning, there's a lot of physician input,** **14 market research, trying to really understand what does** **15 the team want to do, what does the business want the** **16 team to accomplish.**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**
ai073113, (Pages 322:21 to 326:19) **322** **21 Q Would this process have been the general** **22 process used to develop the medical devices Uphold and** **23 Pinnacle?** **24 A Yes, it would.** **323** **1 Q Let's talk a little bit about the proposal** **2 stage. You talk about physician input. Describe for** **3 the jury what that means and how you obtained physician** **4 input at the early stage of a project like this.** **5 A Physician input, physician requirements define** **6 what does the physician require in terms of the product**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

in order to be able to utilize that product in a specific procedure. What are the needs of that physician customer in the product. And a lot of time is spent with physicians at this point, a lot of market research, individual interviews, focus groups, advisory boards are assembled, physicians are presented with concepts, physicians are providing feedback through the development process. This is the start where you're actually defining user requirements for the product. And it precedes actually establishing product -- firm product engineering specifications, in other words, design input requirements. Q So does Boston Scientific document that input that it receives from doctors at this stage? A Absolutely, yes. Q And how is that done? A It's done in many ways. It's done in the form 324 of minutes. It's done in the form of ultimately output specifications. User needs are listed and prioritized and tested again with different groups. They're weighted in a way that ultimately the company can determine what are the most important user needs in the eyes of physicians. And that in turn is used to help design the product and make design trade-offs within the product based on our customers' input. Q Do all products and projects get past this proposal phase? A No. Q And why not? A No, they don't.		

I mean, a business case is being made in the proposal phase that is going to be assessed on its merits, although I would say that relatively -- within Boston Scientific a relatively high majority of projects that enter this product development process does result in some commercialization of a product. And it's primarily because there's a phase -- a process before this process where -- it's referred to as an exploratory -- exploratory program that does a lot of planning and assessment of the business. And the output 325 of that -- successful output of that process, the exploratory process, feeds this proposal phase. So most products are probably going to make it through this, but there are definitely products that don't make it through the process. Q There's physician input at the proposal stage. Is there physician input and does Boston Scientific work with physicians throughout the development process? A Yes. There's really physician input all the way through the point where you're freezing the design and then beyond that where you're actually validating the design. So through the entire process you're reaching out to physicians to get their feedback, review the work that's been done, have them understand and evaluate the product and provide feedback, and if necessary, the product-development team is making changes based on that input.		

20 Q So for the SUI devices like Solyx and Advantage 21 and the pelvic organ prolapse products like Uphold and 22 Pinnacle, describe for the jury how Boston Scientific 23 would get physician feedback through the process. 24 A As an example, one would go out and work with 326 1 physicians to understand what their preferences were 2 relative to products. For instance, you would have them 3 evaluate positives and negatives associated with 4 competitor products so that you would understand what 5 their likes and dislikes are. 6 And then using input that's obtained from the 7 physicians on what they envision a product might look 8 like, you would -- the project team would then go create 9 a series of concept drawings or concept models and again 10 go back out to the clinicians and ask, "How would you 11 evaluate something that might look like this and have 12 these sort of performance characteristics?" and take 13 that feedback back to the project team and then create a 14 next-step prototype and then go back out again to the 15 physician and continue to do that through that 16 development process until you're actually able to 17 produce something that -- a series of physicians, a 18 number of physicians, sometimes 50, sometimes 19 100 physicians, would provide positive feedback.		
ai073113, (Pages 327:17 to 336:17) 327	BSC has previously designated	Plaintiffs adopt and incorporate their counter designations, if any.

17 Q I want to go back to our chart here. The next 18 step in the process is the definition phase. Describe 19 for the jury what that means. 20 A The definition phase is you're zeroing in on 21 the design. You're determining what you want to do and 22 how you want to do it based on physician requirements. 23 You're pulling together various concepts that you're 24 testing out in the marketplace, and you're doing 328 1 laboratory testing. 2 Q And then the next stage says development. What 3 does that mean? 4 A Development is actually when you're translating 5 the input from the customers and taking the concepts and 6 you're putting together specific product design 7 requirements. In other words, what the form, fit, and 8 function of the product is going to be, what the product 9 looks like, how it's going to work. 10 You finalize the design, you verify various 11 aspects of the product either through prototype testing 12 or through evaluation in animals, animal models, and you 13 move towards finalizing freezing that design. 14 At the same time you're starting in parallel 15 with that the process development associated with 16 manufacturing the product. You're developing some 17 prototype manufacturing equipment to produce the product 18 so that ultimately you can manufacture the product in 19 its close-to-final configuration to do some final	this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.	

20 testing to verify the design of the product and verify **21 that that design meets the product specification that** **22 was established up front.** **23 Q For the Boston Scientific slings and POP kits,** **24 does Boston Scientific make -- do biocompatibility** **329** **1 testing to determine whether or not the mesh and the** **2 product is biocompatible?** **3 A Yes. There's an entire organization department** **4 within Boston Scientific that does biocompatibility** **5 work. There's standardized tests that are used to** **6 determine biocompatibility for all materials.** **7 That biocompatibility group has the expertise,** **8 the knowledge, the capability of running batteries of** **9 tests that determine the biocompatibility of the** **10 product -- the material for use in the product.** **11 They also test the materials once they're** **12 actually assembled into the final configuration of a** **13 product, too, because you're concerned also about the** **14 interaction of various materials in a configuration, and** **15 the processes that are used to put those various** **16 materials together can also modify materials. For** **17 instance, if you weld them or heat them or things of** **18 that nature, it can change the characteristic of the** **19 material.** **20 So they have specific biocompatibility tests,** **21 batteries of tests that they put them through. Every** **22 single material at Boston Scientific is handled that** **23 way.** **24 Q And would those tests be done at the**		

330 development stage? A They could be done as early -- if things are well-defined, they could be done as early as late definition phase, but primarily they're done in the development phase. Q And then the next step is validation and scale- up. Tell the jury what that means. A So once the product design is frozen and the product has been verified as meeting its initial product specification -- in other words, it works well, the performance of the product is such that it's as specified and predicted, the product meets those specification requirements -- the decision is made to move into process development work, so all of the equipment associated with manufacturing the product and manufacturing it in such a way that it's extremely repeatable. The process validation work is something that is handled by the manufacturing and engineering team as part of the manufacturing group. And in parallel with that you're preparing for design validation. Design validation is conducted to determine does the product meet the initial user requirements or the physician requirements, the physician needs. 331 And product that's produced on the manufacturing process that's validated, samples are taken from that, and those products are then presented to physicians typically in the form of a test that		

simulates the final use environment, simulates the operating room for instance in this case. And it's conducted by physician customers to determine does the product work as it's specified that it should.

Once that design validation is done and it's understood that the product meets its design requirements, manufacturing is scaled up to a high level.

This is the point at which the product would have been submitted to various regulatory agencies, whether it's the FDA or Japan PMDA, other global regulatory bodies.

And then once the product has passed its final process validation, design validation activity, it moves into a commercialization phase where ultimately it's brought to market.

Q So is it the R&D organization, R&D team that's carrying all of these activities forward, or are there other departments involved as well?

A You know, all product development at Boston

Scientific is done cross-functionally so all functions are represented as part of this process.

Product development, the R&D, the development work associated with a new product, it's the only activity in the company that made use of all functions within the company. All functions participate to some level, some very directly, some indirectly, in the product development process.

Q So what functions would that include?

10 A The core project teams are made up of quality, **11 regulatory, manufacturing, engineering, and certainly** **12 research and development, clinical, marketing. Those** **13 are the primary core members of the team.** **14 Q And what is medical's role in the project team?** **15 A Medical has the responsibility for** **16 understanding risk and completing risk documentation** **17 associated with the product, making an assessment of** **18 risk. So there's a series of documents -- risk** **19 documents that are prepared primarily by the quality** **20 organization but with input from the total team in such** **21 a way.** **22 And then medical then reviews the risk safety** **23 benefit associated with the product as designed and** **24 developed.** **333** **1 Q And then you mentioned clinical. What would** **2 clinical's role be in the project team?** **3 A Clinical is determining, you know, what is** **4 necessary in terms of potential clinical testing and** **5 when clinical testing should occur with that new product** **6 or that product modification.** **7 Most of the time in the division, urology** **8 women's health, because the product was a -- what's** **9 referred to as a simple 510(k) regulatory pathway, that** **10 doesn't require clinicals until -- it doesn't require** **11 clinicals to be approved by the agency.** **12 Clinical trials are done after launch, but in** **13 some instances where there's a different regulatory** **14 pathway known as a PMA there are clinical trials**		

15 conducted on the products before they come to market. **16 Q If you'd turn over to Slide 23 for me, this** **17 slide talks about and describes something called a** **18 design review. Tell the jury what a design review is.** **19 A A design review is an ascertation by the core** **20 team plus other key individuals. That ascertains is the** **21 product meeting its design input requirements, is it** **22 moving through this phase gate process in such a way** **23 that's appropriate. And by "appropriate" I mean it** **24 meets the standard operating procedures of the division.** **334** **1 And typically the project team -- or the** **2 project team is required to bring in independent** **3 reviewers associated with design reviews to assure that** **4 there's no bias in terms of the project, the project** **5 team. And those reviewers are very critical of the** **6 design elements that are being presented.** **7 It can be associated with design and** **8 development. It can be associated with product** **9 specification there's a design review. In other words,** **10 when you put together the design specification, form,** **11 fit, and function of the product, it's reviewed in a** **12 design review and challenged.** **13 At the design freeze, very important, design** **14 review where the product is virtually complete from a** **15 design perspective, from that standpoint. And there's a** **16 lot of -- it is an extensive design review with a lot of** **17 challenge relative to the design. Design verification,**		

18 design review, first human use, and then a design **19 transfer is the transfer of the product to manufacturing** **20 or operation.** **21 Q So there would be these reviews at various** **22 points in time during the development process?** **23 A There would be.** **24 Q And were these design reviews done during the** **335** **1 development of Boston Scientific's slings and pelvic** **2 organ prolapse devices?** **3 A They were.** **4 Q Why -- The process, the five-step process, why** **5 is that process used at Boston Scientific? Why use that** **6 process? What's the purpose?** **7 A It's a process that's used not only in medical** **8 device development. It's a process that's used in** **9 development of many new products across multiple** **10 industries.** **11 The reason it's done is it's a tried and true** **12 process. It's very successful. It's a way to challenge** **13 the engineering teams, challenge the assumptions, to be** **14 assured that the work that's being done is appropriate** **15 and meets specification.** **16 Within Boston Scientific, there are key** **17 elements in the medical device design and development** **18 that are unique, of course. It's critical that the** **19 design history file work meet what's referred to by the** **20 FDA as design controls.** **21 And the FDA puts design control guidance** **22 procedures in place that medical-device companies follow** **23 in such a way to be assured that the right**		

24 considerations for physician and patient are kept in **336** **1 mind as the product is being developed.** **2 Q When designing products at Boston Scientific** **3 like the sling products and the pelvic organ prolapse** **4 products, what is the goal? What is the focus? What** **5 are you trying to accomplish through the R&D process?** **6 A Well, what you're trying to do is you're trying** **7 to develop a product that meets a physician user need.** **8 You're trying to develop a product that in some way** **9 improves the procedure, makes it safer, makes it easier,** **10 and makes it faster. Faster will reduce anesthesia** **11 times which means there will be lower risk, for** **12 instance, for a patient.** **13 You're trying to improve upon the product in** **14 such a way that it's differentiated, ultimately from a** **15 business perspective may be more competitive. All those** **16 factors are put into play when defining a product and** **17 then ultimately developing and commercializing it.**		
ai073113, (Page 337:3 to 337:10) **337** **3 Q Do you believe that the research and** **4 development process at Boston Scientific produced safe** **5 and effective medical devices to treat pelvic organ** **6 prolapse?** **7 A I do.** **8 Q And included in those products would be the** **9 Uphold and Pinnacle lines?** **10 A Correct.**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate the objections set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

1. **Objections to Counter Exhibits.**

a. Intoccia 451 and 471 have been previously identified by BSC. Plaintiffs adopt and incorporate their objections as set forth in their counter-designations, if any.

2. **Counter Exhibits to Counter Exhibits**

a. Plaintiffs adopt and incorporate the exhibits designated in counter designations regarding this witness.

DATED: July 20, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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